K091566

OCT 2 8 2009

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Warsaw, IN 46581-0708
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Summary of Safety and Effectiveness

Sponsor:	Zimmer, GmbH SulzerAllee 8 Winterthur, Switzerland CH-8404
Contact Person:	Daniel J. Williman Specialist, Regulatory Affairs Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	May 27, 2009
Trade Name:	*Zimmer® Natural Nail*™ System Cephalomedullary Nails
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Intramedullary fixation rod, product code HSB 21 CFR § 888.3020
Predicate Devices:	*Zimmer Natural Nail* System Piriformis Fossa & Greater Trochanter Antegrade Femoral Nails, manufactured by Zimmer, Inc. (K083497, cleared February 19, 2009) *I.T.S.T.*™ Intertrochanteric Subtrochanteric Intramedullary Femoral Nail, manufactured by Zimmer, Inc. (K032367, cleared August 12, 2003) Intramedullary Nail System, manufactured by Zimmer, Inc. (K965098, cleared February 28, 1997)
Device Description:	The *Zimmer Natural Nail* System Cephalomedullary Nails are a family of temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. The nails are available in a variety of lengths and diameters to meet assorted anatomical needs. Each of the intramedullary nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections of each nail. Nail caps

	are available to prevent tissue ingrowth into nail threads and increase the length of the nail if desired.
Intended Use:	The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone. Indications for use of the Cephalomedullary nails include: • Compound and simple shaft fractures • Proximal, metaphyseal and distal shaft fractures • Segmental fractures • Comminuted fractures • Fractures involving osteopenic and osteoporotic bone • Pathological fractures • Fractures with bone loss • Pseudoarthrosis, non-union, mal-union and delayed union • Periprosthetic fractures • Surgically created defects such as osteotomies • Intertrochanteric and subtrochanteric fractures
Comparison to Predicate Device:	The *Zimmer Natural Nail* System Cephalomedullary Nails are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate device(s).
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Zimmer, GmbH
% Mr. Daniel J. Williman
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

OCT 2 8 2009

Re: K091566
Trade/Device Name: Zimmer Natural Nail™ System Cephalomedullary Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: October 7, 2009
Received: October 8, 2009

Dear Mr. Williman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091566/S002

Indications for Use

510(k) Number (if known):

Device Name:
Zimmer® Natural Nail™ System Cephalomedullary Nails

Indications for Use:

The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone.

Indications for use of the Cephalomedullary nails include:
- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091566

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)